

REMARKS

In reply to the Office Action dated September 27, 2004, claims 1, 3-4, 6-9, 11-12, 37-39, and 41-42 are currently under examination in the Application. By the above amendment, claims 3, 6, 11, and 37-38 have been canceled, claims 1, 4, 7, 8, 9, 12, 39, 41, and 42 have been amended, and claims 43-50 have been added. Support for the amendments can be found throughout the specification as filed. In particular, support for "an absence outwardly of any visible symptoms of lung damage" can be found, for example, at page 9, lines 20-21. No new matter has been added. The above amendment is not to be construed as acquiescence to the stated grounds for objection/rejection and is made without prejudice to prosecution of any subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application.

***Claim Objections***

Claims 3 and 4 are objected to as allegedly being of improper dependent form. In particular, the Action contends that the limitations recited in claims 3 and 4 do not further limit the claims.

Without acquiescing to the grounds for objection, claim 3 has been canceled and claim 4 has been amended to depend from claim 1. Applicants note that this amendment is made without prejudice and solely to expedite prosecution. Applicants reserve the right to prosecute any subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application. Applicants respectfully submit that the objection has been obviated.

***Claim Rejections – 35 U.S.C. § 112, first paragraph (new matter)***

Claims 1, 3-4, 6-9, 11-12, 37-39, and 41-42 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Applicants, at the time the application was filed, had possession of the claimed invention. In particular, the Action alleges that there is no support in the specification as filed for the negative proviso "which

mammal is not exhibiting a symptom specific to lung damage". The Action contends that there is no disclosure of symptoms of lung damage *per se* in the specification and therefore, the symptoms are not "positively recited" alternative elements in the specification, elements allegedly required for a negative proviso.

Without acquiescing to the grounds for rejection and without prejudice, Applicants have amended the claims to recite "in which mammal there is an absence outwardly of any visible symptoms of lung damage." Support for the amendment can be found in the specification as filed, for example, at page 9, lines 20-21. Applicants submit that the skilled artisan would readily appreciate that Applicants were in possession of the claimed invention in view of the present disclosure. Accordingly, Applicants respectfully submit that the rejection has been obviated and may be properly withdrawn.

***Claim Rejections – 35 U.S.C. § 112, second paragraph (indefiniteness)***

Claims 1, 3-4, 6-9, 11-12, 37-39, and 41-42 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the Action contends that since the specification allegedly does not teach which symptoms are specific to lung damage, the metes and bounds of the patient population provided by this negative exclusion cannot be ascertained. Further, with regard to claim 8, the Action contends that the claim limitation makes no sense in that if the mammal has lung damage and one is monitoring for changes in the extent of such damage, then the mammal would necessarily have a symptom specific to lung damage. Concerning claims 41 and 42, the Action alleges that the specification fails to define or describe the metes and bounds of the time period "in which the onset of lung damage cannot otherwise be confirmed without the aid of one or more invasive procedures". Lastly, the Action points out that the independent claims lack antecedent basis for "the body fluid" and suggests that Applicants amend them to recite "a body fluid".

Applicants respectfully traverse the rejection.

As an initial matter, Applicants note that claims 1 and 8 have been amended. Applicants submit that the skilled artisan would readily understand the metes and bounds of the

presently claimed invention. Accordingly, Applicants submit that the rejection with regard to these claims has been obviated. Applicants note that this amendment is made without prejudice and solely to expedite prosecution. Applicants reserve the right to prosecute any subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application.

With regard to the rejection of claims 41 and 42, Applicants submit that “A decision on whether a claim is invalid [for indefiniteness] requires a determination of whether **those skilled in the art** would understand what is claimed when the claim is read in light of the specification”. *Rhone-Poulenc Agrochimie S.A. v Biagro Western Sales Inc.*, 35 U.S.P.Q.2d 1203, 1205 (Ca. 1994) (emphasis added). Applicants submit that the skilled artisan (*i.e.*, a clinician) would readily understand the time period recited in the claims, that is, the time period in which the onset of lung damage cannot otherwise be confirmed without the aid of one or more invasive procedures, particularly in view of the teachings of the specification as filed. Applicants submit that the claims are not indefinite and respectfully request withdrawal of the rejection.

Concerning the lack of antecedent basis for “the body fluid”, Applicants thank the Examiner for noting this inadvertent error. Applicants have amended the claims as suggested to recite “a body fluid” in the independent claims. Accordingly, Applicants submit that the rejection has been obviated and may be properly withdrawn.

Applicants submit that the pending claims satisfy the requirements under 35 U.S.C. § 112, second paragraph and respectfully request withdrawal of the rejections under this section.

***Claim Rejections – 35 U.S.C. § 102(b)***

Claims 1, 3-4, 6-9, 11-12, 37-39, and 41-42 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Doyle *et al.* (Advances in Critical Care Testing, Eds. Muller and McQueen, Springer-Verlag Telos, January 1997). The Action asserts that Doyle *et al.* teach screening for increases in SP-A and SP-B in a variety of patients including normal individuals and ventilated patients, thereby allegedly meeting all the limitations of the claims.

Applicants respectfully traverse the rejection on the following grounds.

Applicants note that the independent claims have been amended to recite “said method comprising screening for an increase in the level of SP-B in a body fluid of said mammal relative to a normal reference level.” Applicants submit that Doyle *et al.* do not show any significant difference in SP-B levels between the control group and the OD patient group. Specifically, Table 1 discloses that the SP-B level in the control group is 1685 ng/ml  $\pm$  58 while the SP-B level in the OD patient group is 1829 ng/ml  $\pm$  635. Thus, in fact, Doyle *et al.* show that SP-B levels do not increase in the OD patient group. Doyle *et al.* only show that SP-B increases in the APE and ARDS patient groups. The OD group is the group with “no evidence of cardiorespiratory disease” which, by the Action’s own assertions at page 5 of the Office Action, is seen to meet the limitation of “not exhibiting a symptom specific to lung damage” and is also evidence of disease “during a period in which the onset of lung damage cannot otherwise be confirmed without the aid of one or more invasive procedures”. Applicants submit that this assertion could also be extended to the limitations currently recited in the claims, *e.g.*, “an absence outwardly of any visible symptoms of lung damage” and “early stage lung damage”. Thus, Applicants submit that Doyle *et al.* do not disclose a method for diagnosing or monitoring lung damage in a mammal in which there is an absence outwardly of any visible symptoms of lung damage or during a period in which the onset of lung damage cannot otherwise be confirmed without the aid of one or more invasive procedures, or a method for diagnosing or monitoring early stage lung damage, comprising measuring the levels of SP-B. Accordingly, Applicants submit that the cited reference does not anticipate the claimed invention and respectfully request withdrawal of the rejection.

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Reply to Office Action dated September 27, 2004

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that all the claims remaining in the application are now believed allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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